

REMARKS

This application is a national phase filing under 35 U.S.C. §371 of International Application No. PCT/JP2004/019226 filed May 30, 2007. The PCT application, with an International Filing date of December 22, 2004, claims priority to Japanese Patent Application Serial No. 2003-425706, filed December 22, 2003. At the time the application was filed, claims 1-6 were pending and claims 1, 4 and 5 were amended in a Preliminary Amendment filed with the application. Claim 1 and Claim 6 are amended above, claims 2 and 4 are canceled and new claims 7- 10 are added. Claims 1, 3 and 5-10 are currently pending in the application.

Japanese Priority Document

Submitted with this response is a copy of the Japanese priority document referenced in this application as filed, via preliminary amendment. Specifically, an English translation of Japanese Patent Application Serial No. 2003-425706 is submitted in accordance with 37 C.F.R. 1.55.

Objections to Drawing

The office action states that Figure 1 was objected to because it failed to show units that define the X and Y axes of the graph. Figure 1 has been amended to provide a label for the Y-axis, specifically “Absorbance at 450 nm.” Support for this label is found in paragraph [0039] of the present specification. The X axis already had a label, namely “Units” and this label remains unamended.

Rejections under 35 U.S.C. §112, second paragraph

Claim 1 was rejected as “vague and indefinite in being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections.” Specifically, the examiner states that it is unclear what essential structural and functional cooperative relationships exist between von Willebrand factor cleaving protease and either one of thrombosis and degree of thrombocytopenia. As stated in paragraphs [0013] and [0016] of the specification, a decreased amount of von Willebrand factor-cleaving protease correlates to an increased severity, or degree, of thrombophilia. Further, the

term “thrombophilia” means the propensity to develop thrombosis, or blood clots. Thus, the relationship between “thrombosis” and “thrombophilia” is that one is a condition and the other is the propensity to develop that condition.

Claim 1 was also rejected as “indefinite in being incomplete for omitting essential steps, such omission amounting to a gap between the steps.” In particular, the examiner states that a correlation step which correlates a measured value of von Willebrand factor-cleaving protease and thrombosis or degree of thrombophilia is missing. As stated in response to the first rejection of claim 1, paragraphs [0013] and [0016] explain that a decreased level of von Willebrand factor-cleaving protease correlates to an increased degree of thrombophilia. In other words, when a decrease in the levels of von-Willebrand factor-cleaving protease is detected, this means that the patient is exhibiting an increased degree of thrombophilia and thus is at greater risk of blood clots. Claim 1 was amended to explicitly provide for this correlation step.

Claim 1 was also rejected by the examiner because the examiner believes it is unclear whether or not the claimed method is a qualitative or quantitative diagnostic method and whether an increase or a decrease in the level of von Willebrand factor-cleaving protease is detected. As stated in paragraph [0010], the term “analyze” includes a detection to judge a presence or absence of a substance to be analyzed and a measurement to quantitatively or semi-quantitatively determine an amount of a substance to be analyzed. Paragraph [0010] also discloses that some embodiments of the invention use antibodies or autoantibodies to make this measurement. The method of the present invention detects a change in the levels of von Willebrand-cleaving protease, meaning either an increase or a decrease. In accordance with this, claims 1 and 6 have been amended to include the term “analyze.”

Claim 1 was also rejected because the examiner was unclear as to how the claimed method could differentially detect thrombosis and degree of thrombophilia “which are different diseases or conditions.” Thrombophilia is the propensity to develop thrombosis, or blood clots. Thus, the two terms are not “different diseases or conditions,” rather, thrombosis is a condition and thrombophilia is the propensity to develop that condition. Claims 1 has been amended in order to provide greater clarity on this point.

Claim 1 was also rejected as ambiguous because the examiner claims that the source of the analyte (i.e. the type of sample) is not defined. Claim 1 has been amended to indicate the source of the analyte.

The office action says that claims 2 and 4 were rejected, for various reasons. Claims 2 and 4 have been canceled.

Claim 6 was rejected as indefinite in reciting “A kit...characterized by comprising...” because its scope was unclear. Claim 6 has been amended to address this concern.

Rejections under 35 U.S.C. §102

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *See Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984).

The office action states that claims 1, 2, 4 and 5 were rejected under 35 U.S.C. §102(b) as anticipated by Konetschny et al (Development of a Highly Sensitive and Specific Enzyme-linked Immunosorbent Assay for the Detection of ADAMTS-13 in Human Plasma, Blood, 102 (11) Abstract #4062). In order to be anticipating under 35 U.S.C. 102(b), a reference must be teach every aspect of the claimed invention either explicitly or impliedly and any feature not directly taught must be inherently present. MPEP 706.02(V). A 102(b) rejection can be overcome by, *inter alia*, by amending the claims to patentably distinguish over the asserted prior art, or by persuasively arguing that the claims are patentably distinguishable from the prior art. MPEP 706.02(b).

Applicant has amended claim 1 and canceled claims 2 and 4. Claim 1 is independent. Specifically, applicant has amended claim 1 to require that the patient analyzed suffers from one or more of the following conditions: acute or chronic myeloid leukemia, acute promyelotic

leukemia, pulmonary embolism, cerebral infarction, veno-occlusive disease, acute lymphocytic leukemia, and deep vein thrombosis. The Konetschny reference does not teach using an anti-von Willebrand factor-cleaving protease to detect the degree of thrombophilia in patients suffering from these diseases or conditions. Applicant respectfully submits that the amendments to claims 1 and 5 patentably distinguish over the Konetschny reference.

The office action also states that claims 1, 2, and 4-6 are rejected under 35 U.S.C. §102 (b) as anticipated by Scheiflinger et al (US 2004/0214346 A1).

Applicant has amended claims 1 and 6 and canceled claims 2 and 4. Claims 1 and 6 are independent. Specifically, applicant has amended claim 1 to require that the patient analyzed suffers from one or more of the following conditions: acute or chronic myeloid leukemia, acute promyelotic leukemia, pulmonary embolism, cerebral infarction, veno-occlusive disease, acute lymphocytic leukemia, and deep vein thrombosis. Further, the applicant has amended claim 6 to include a requirement for instructions to use the antibody on a sample of bodily fluid taken from a patient suffering from one or more of the following conditions: acute or chronic myeloid leukemia, acute promyelotic leukemia, pulmonary embolism, cerebral infarction, veno-occlusive disease, acute lymphocytic leukemia, and deep vein thrombosis. The Scheiflinger reference does not teach using an anti-von Willebrand factor-cleaving protease to detect the degree of thrombophilia in patients suffering from these diseases or conditions. Applicant respectfully submits that the amendments to claims 1, 5 and 6 patentably distinguish over the Scheiflinger reference.

The examiner also rejected claims 1, 2, and 4-6 under 35 U.S.C. §102(a) as anticipated by Soejima et al. (EP 1 544 293). Applicant has amended claims 1 and 6 and canceled claims 2 and 4. Claims 1 and 6 are independent. In order to be an anticipating reference under 102(a), the following situation must be true: “the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.” Applicant respectfully submits that this is not the case. Specifically, with regard to the “known or used” provision of the statute, the knowledge or use imputed by the Soejima reference did not occur *in this country* before the invention by the applicants. Further, with regard to the “patented or described in a printed publication” portion of the statute, the Soejima reference cannot qualify as a patent or printed publication at least until it issues or is published (whichever occurs first) and

the Soejima reference was not published until June 22, 2005, well after the current application's filing date of December 22, 2004. Further, with the submission of an English translation of the Japanese priority document in accordance with 37 C.F.R. 1.55, this application is now entitled to a priority date of December 22, 2003. As such, the Soejima reference is not prior art under 102(a).

Finally, the office action states that claims 1-6 are rejected under 35 U.S.C. §102(e) as anticipated by Igami et al (US 2009/0220990). In order to be an anticipating reference under 102(e), a reference must have an effective date that is earlier than the priority date of the application at issue. Applicant respectfully submits that the filing date of this application, December 22, 2004, is earlier than the 102(e) effective date of the Igami reference, namely the international filing date of February 15, 2007. Further, this application is now entitled to a priority date of December 22, 2003, with the submission of an English translation of the Japanese priority document. As such, the Igami reference is not prior art under 35 U.S.C. 102(e).

It is respectfully submitted that the above-identified application is now in a condition for allowance and favorable reconsideration and prompt allowance of these claims are respectfully requested. Should the Examiner believe that anything further is desirable in order to place the application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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